

Listing of claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claims 1-66 (cancelled).

Claim 67 (new): A quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance, which has a solubility of at the most 0.1 % w/v in 0.1 N hydrochloric acid at room temperature,

the composition being based on a powder comprising the therapeutically and/or prophylactically active substance and having such a particle size that, when the powder is subjected to a sieve analysis, then at least 90% w/w of the particles passes through sieve 180 µm, the powder being contacted with an aqueous medium to form a particulate composition, which has such a particle size that, when the particulate composition is subjected to a sieve analysis, then at least 50% w/w of the particles passes through sieve 180 µm, and

the composition, when tested in accordance with the dissolution method I defined herein employing 0.07 N hydrochloric acid as dissolution medium, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

Claim 68 (new): A quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance which has a solubility of at the most 0.1 % w/v in 0.1 N hydrochloric acid at room temperature,

the composition being in the form of a particulate composition or being based on a particulate composition which is obtained by contacting a powder comprising the

therapeutically and/or prophylactically active substance with an aqueous medium in such a manner that the mean particle size of the particles of the particulate composition is at the most 100% larger than the mean particle size of the powder before contact with the aqueous medium, and

the composition, when tested in accordance with the dissolution method I defined herein employing 0.07 N hydrochloric acid as dissolution medium, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

Claim 69 (new): A quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance which has a pK_a value of at the most 5.5,

the composition being based on a powder comprising the therapeutically and/or prophylactically active substance and having such a particle size that, when the powder is subjected to a sieve analysis, then at least 90% w/w of the particles passes through sieve 180 µm, the powder being contacted with an aqueous medium to form a particulate composition, which has such a particle size that, when the particulate composition is subjected to a sieve analysis, then at least 50% w/w of the particles passes through sieve 180 µm, and

the composition, when tested in accordance with the dissolution method I defined herein, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

Claim 70 (new): A quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance which has a pK_a value of at the most 5.5,

the composition being in the form of a particulate composition or being based on a particulate composition which is obtained by contacting a powder comprising the therapeutically and/or prophylactically active substance with an aqueous medium in such a manner that the mean particle size of the particles of the particulate composition is at the most 100% larger than the mean particle size of the powder before contact with the aqueous medium, and

the composition, when tested in accordance with the dissolution method I defined herein, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

Claim 71 (new): A composition according to any one of claims 67, 68, 69 and 70, wherein the composition, when subjected to dissolution method I as defined herein employing 0.07 N hydrochloric acid as dissolution medium, releases at least 55% w/w of total amount of active substance present in the composition within the first 20 minutes of the test.

Claim 72 (new): A composition according to any one of claims 67, 68, 69 and 70, wherein the solubility of the therapeutically and/or prophylactically active substance in 0.1 N hydrochloric acid at room temperature is at the most 0.05% w/v.

Claim 73(new): A composition according to any one of claims 67, 68, 69 and 70, wherein the aqueous medium comprises water and an organic solvent.

Claim 74 (new): A composition according to any one of claims 67, 68, 69 and 70, wherein the mean particle size of the particles of the particulate composition is at the most 250 μm , after contact with an aqueous medium.

Claim 75 (new): A composition according to any one of claims 67, 68, 69 and 70, further comprising at least one pharmaceutically acceptable excipient.

Claim 76 (new): A composition according to claim 75, wherein the at least one pharmaceutically acceptable excipient is selected from the group consisting of binders, disintegrants, fillers and diluents.

Claim 77 (new): A composition according to claim 76, wherein the composition comprises a filler having binding properties.

Claim 78 (new): A composition according to claim 76, wherein the filler having binding properties is, e.g., lactose (such as, e.g., Tabletose®, Pharmatose®), sugar derivatives (such as, e.g., mannitol, sorbitol), calcium carbonate (CaCO_3), tricalcium phosphate ($\text{Ca}_3(\text{PO}_4)_2$), calcium hydrogen phosphate (CaHPO_4) (such as, e.g., Di-Cafos®, Di-Tab®, Emcompress® or Pharmacompress®), or the like and/or mixtures thereof.

Claim 79 (new): A composition according to claim 76, wherein the filler having binding properties is calcium hydrogen phosphate.

Claim 80 (new): A composition according to claim 76, wherein the filler having binding properties as raw material has a mean particle size of at the most 140 μm .

Claim 81 (new): A composition according to any one of claims 67, 68, 69 and 70, further comprising an alkaline substance such as, e.g., an antacid or an antacid-like substance.

Claim 82 (new): A composition according to claim 81, wherein the alkaline substance is an antacid or an antacid-like substance such as, e.g., sodium hydrogen carbonate,

magnesium carbonate, magnesium hydroxide or magnesium metasilicate aluminate or mixtures thereof.

Claim 83 (new): A composition according to claim 81, wherein the mean particle size of the antacid-like substance as raw material is at the most 250 µm.

Claim 84 (new): A composition according to claim 77, wherein the filler having binding properties is, e.g., lactose (such as, e.g., Tabletose®, Pharmatose®), sugar derivatives (such as, e.g., mannitol, sorbitol), calcium carbonate (CaCO_3), tricalcium phosphate ($\text{Ca}_3(\text{PO}_4)_2$), calcium hydrogen phosphate (CaHPO_4) (such as, e.g., Di-Cafos®, Di-Tab®, Emcompress® or Pharmacompress®), or the like and/or mixtures thereof.

Claim 85 (new): A composition according to any one of claims 67, 68, 69 and 70, wherein the therapeutically and/or prophylactically active substance is a non-steroid anti-inflammatory drug substance (NSAID substance).

Claim 86 (new): A composition according to any one of claims 67, 68, 69 and 70, wherein the therapeutically and/or prophylactically active substance is selected from the group consisting of lornoxicam, diclofenac, nimesulide, ibuprofen, piroxicam, piroxicam (betacyclodextrin), naproxen, ketoprofen, tenoxicam, aceclofenac, indometacin, nabumetone, acemetacin, morniflumate, meloxicam, flurbiprofen, tiaprofenic acid, proglumetacin, mefenamic acid, fenbufen, etodolac, tolfenamic acid, sulindac, phenylbutazone, fenoprofen, tolmetin, acetylsalicylic acid, dexibuprofen, paracetamol, and pharmaceutically acceptable salts, complexes and/or prodrugs thereof and mixtures thereof.

Claim 87 (new): A composition according to any one of claims 67, 68, 69 and 70, wherein the therapeutically and/or prophylactically active substance is lornoxicam or a pharmaceutically acceptable salt, complex or prodrug thereof.

Claim 88 (new): A composition according to any one of claims 67, 68, 69 and 70, comprising a further active drug substance.

Claim 89 (new): A composition according to claim 88, wherein the further active drug substance is an antidepressant, an opioid, a prostaglandine analogue (e.g. misoprostol), a glucocorticosteroid, a cytostaticum (e.g. methotrexate), a H₂ receptor antagonist (e.g. cimetidine, ranitidine), a proton pump inhibitor (e.g. pantoprazole, omeprazole, lansoprazole) and/or an antacidum.

Claim 90 (new): A composition according to claim 88, wherein the further active drug substance is paracetamol, penicillamine, sulfasalazine and/or auranofin.

Claim 91 (new): A composition according to any one of claims 67, 68, 69 and 70, in unit dosage form, wherein the unit dosage of the composition comprises from 1 to 32 mg of the therapeutically and/or prophylactically active substance.

Claim 92 (new): A composition according to any one of claims 67, 68, 69 and 70 in unit dosage form, wherein the unit dosage comprises from 1 mg to 1.6 g of the therapeutically and/or prophylactically active substance.

Claim 93 (new): A composition according to any one of claims 67, 68, 69 and 70, wherein the therapeutically and/or prophylactically active substance is lornoxicam and a unit dosage of the composition contains 4, 8, 12, 16, 20, 24, 28, 32 or 36 mg of lornoxicam.

Claim 94 (new): A composition according to any one of claims 67, 68, 69 and 70, wherein the water content in the composition is at the most 5% w/w determined by the LOD (loss on drying) method described herein.

Claim 95 (new): A composition according to any one of claims 67, 68, 69 and 70, comprising sodium hydrogen carbonate.

Claim 96 (new): A composition according to any one of claims 67, 68, 69 and 70, comprising calcium hydrogen phosphate.

Claim 97 (new): A method for the preparation of a composition according to any one of claims 67, 68, 69 and 70, the method comprising the steps of

- i) mixing the therapeutically and/or prophylactically active substance with a) an alkaline substance, b) a filler having binding properties, and, optionally, c) other pharmaceutically acceptable excipients to obtain a powder mixture,
- ii) contacting the thus obtained powder mixture with an aqueous medium to obtain a wet powder,
- iii) drying the thus obtained wet powder at a temperature above room temperature until the water content in the powder is at the most 5% w/w determined as described herein, to obtain a first particulate mixture,
- iv) sieving the thus obtained first particulate mixture,

- v) optionally, adding any further pharmaceutically acceptable excipients to obtain a second particulate mixture,
- vi) optionally, compressing the thus obtained second particulate mixture into tablets, and
- vii) optionally, coating the thus obtained tablets.

Claim 98 (new): A method according to claim 97, wherein the alkaline substance employed in step i) is an antacid-like substance such as, e.g., sodium hydrogen carbonate, magnesium carbonate, magnesium hydroxide or magnesium metasilicate aluminate or mixtures thereof.

Claim 99 (new): A method according to claim 97, wherein the filler having binding properties is, e.g., lactose (such as, e.g., Tabletose®, Pharmatose®), sugar derivatives (such as, e.g., mannitol, sorbitol), calcium carbonate (CaCO_3), tricalcium phosphate, calcium hydrogen phosphate (CaHPO_4) (such as, e.g., Di-Cafos®, Di-Tab®, Emcompress® or Pharmacompress®), or the like and/or mixtures thereof.

Claim 100 (new): A method according to claim 97, wherein the aqueous medium employed in step ii) is a solvent comprising water and an organic solvent.

Claim 101 (new): A method according to claim 100, wherein the organic solvent is a solvent which is miscible with water such as, e.g., a branched or unbranched lower (C_1-C_5) aliphatic alcohol like, e.g., ethanol, methanol, isopropanol, 1-propanol, 1-butanol, 2-butanol, iso-butanol, tert. butanol and 1-pentanol, 2-pentanol, 3-pentanol, iso-pentanol and tert. pentanol and mixtures thereof.

Claim 102 (new): A method according to claim 100, wherein the concentration of the organic solvent in the solvent is from 0% v/v to 95% v/v.

Claim 103 (new): A method according to claim 97, wherein the mean particle size of the particles of the first particulate mixture is at the most 100% larger than the mean particle size of the powder mixture from step i) before subjecting the powder mixture to the reaction in the aqueous medium employed in step ii).

Claim 104 (new): A method according to claim 97, wherein the mean particle size of the particle of the first particulate mixture is at the most 90% larger than the mean particle size of the powder mixture from step i) before subjecting the powder mixture to the reaction in an aqueous medium employed in step ii).

Claim 105 (new): A method according to claim 97, wherein the powder obtained in step i) has such a particle size that - when the powder is subjected to a sieve analysis - then at least 90% w/w of the particles passes through sieve 180 µm, and the first particulate mixture obtained in step iii) has such a particle size that - when the particulate composition is subjected to a sieve analysis - then at least 50% w/w of the particles passes through sieve 180 µm.

Claim 106 (new): A method according to claim 97, wherein the mean particle size of the particles of the first particulate mixture is at the most 250 µm.

Claim 107 (new): A method for treatment and/or prophylaxis of acute pain and/or mild or moderate pain comprising administering to a patient an effective amount of a therapeutically and/or prophylactically active substance in the form a quick release composition according to any one of claims 67, 68, 69 and 70.